

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Advisory Committee for Reproductive Health Drugs (ACRHD)

FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center
(Rm. 1503), Silver Spring, MD

March 4, 2013 (Morning Session)

DRAFT QUESTIONS

1. **(VOTE)** Based on the pre-specified analyses, is there sufficient evidence to conclude that gabapentin is effective in treating moderate to severe vasomotor symptoms (VMS) due to menopause?
 - a. Please provide a rationale for your vote and, if applicable, any additional recommendations.
2. **(VOTE)** Is the overall risk/benefit profile of gabapentin acceptable to support approval of this product for the proposed indication?
 - a. Please provide a rationale for your vote and, if applicable, any additional recommendations.